

# 2002. évi VI. törvény

## az Európa Tanácsnak az emberi lény emberi jogainak és méltóságának a biológia és az orvostudomány alkalmazására tekintettel történő védelméről szóló, Oviedóban, 1997. április 4-én kelt Egyezménye: Az emberi jogokról és a biomedicináról szóló Egyezmény, valamint az Egyezménynek az emberi lény klónozásának tilalmáról szóló, Párizsban, 1998. január 12-én kelt Kiegészítő Jegyzőkönyve kihirdetéséről<sup>1</sup>

Hatályos: 2002. 05. 01. –

1. § Az Országgyűlés az Európa Tanácsnak az emberi lény emberi jogainak és méltóságának a biológia és az orvostudomány alkalmazására tekintettel történő védelméről szóló, Oviedóban, 1997. április 4-én kelt Egyezménye: Az emberi jogokról és a biomedicináról szóló Egyezményt (a továbbiakban: Egyezmény), valamint az Egyezménynek az emberi lény klónozásának tilalmáról szóló, Párizsban, 1998. január 12-én kelt Kiegészítő Jegyzőkönyvét (a továbbiakban: Jegyzőkönyv) e törvénnyel hirdeti ki. *(A megerősítésről szóló okirat letétbe helyezése 2002. január 9-én megtörtént.)*

2. § Az Egyezmény angol nyelvű szövege és annak hivatalos magyar nyelvű fordítása a következő:

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### **Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine:**

#### **Convention on Human Rights and Biomedicine**

##### *Preamble*

The Member States of the Council of Europe, the other States and the European Community signatories hereto,  
bearing in mind the Universal Declaration of Human Rights proclaimed by the General Assembly of the United Nations on 10 December 1948,  
bearing in mind the Convention for the Protection of Human Rights and Fundamental Freedoms of 4 November 1950,  
bearing in mind the European Social Charter of 18 October 1961,  
bearing in mind the International Covenant on Civil and Political Rights and the International Covenant on Economic, Social and Cultural Rights of 16 December 1966,  
bearing in mind the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data of 28 January 1981,  
bearing also in mind the Convention on the Rights of the Child of 20 November 1989,  
considering that the aim of the Council of Europe is the achievement of a greater unity between its members and that one of the methods by which that aim is to be pursued is the maintenance and further realisation of human rights and fundamental freedoms,  
conscious of the accelerating developments in biology and medicine,  
convinced of the need to respect the human being both as an individual and as a member of the human species and recognising the importance of ensuring the dignity of the human being,  
conscious that the misuse of biology and medicine may lead to acts endangering human dignity,  
affirming that progress in biology and medicine should be used for the benefit of present and future generations,  
stressing the need for international co-operation so that all humanity may enjoy the benefits of biology and medicine,  
recognising the importance of promoting a public debate on the questions posed by the application of biology and medicine and the responses to be given thereto,  
wishing to remind all members of society of their rights and responsibilities,  
taking account of the work of the Parliamentary Assembly in this field, including Recommendation 1160 (1991) on the preparation of a Convention on bio-ethics,  
resolving to take such measures as are necessary to safeguard human dignity and the fundamental rights and freedoms of the individual with regard to the application of biology and medicine  
have agreed as follows:

## Chapter I

### *GENERAL PROVISIONS*

#### *Article 1*

##### *Purpose and object*

Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine.

Each Party shall take in its internal law the necessary measures to give effect to the provisions of this Convention.

#### *Article 2*

##### *Primacy of the human being*

The interests and welfare of the human being shall prevail over the sole interest of society or science.

#### *Article 3*

##### *Equitable access to health care*

Parties, taking into account health needs and available resources, shall take appropriate measures with a view to providing, within their jurisdiction, equitable access to health care of appropriate quality.

#### *Article 4*

##### *Professional standards*

Any intervention in the health field, including research, must be carried out in accordance with relevant professional obligations and standards.

## Chapter II

### *CONSENT*

#### *Article 5*

## *General rule*

An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks. The person concerned may freely withdraw consent at any time.

## *Article 6*

### *Protection of persons not able to consent*

1. Subject to Articles 17 and 20 below, an intervention may only be carried out on a person who does not have the capacity to consent, for his or her direct benefit.

2. Where, according to law, a minor does not have the capacity to consent to an intervention, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law.

The opinion of the minor shall be taken into consideration as an increasingly determining factor in proportion to his or her age and degree of maturity.

3. Where, according to law, an adult does not have the capacity to consent to an intervention because of a mental disability, a disease or for similar reasons, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law.

The individual concerned shall as far as possible take part in the authorisation procedure.

4. The representative, the authority, the person or the body mentioned in paragraphs 2. and 3. above shall be given, under the same conditions, the information referred to in Article 5.

5. The authorisation referred to in paragraphs 2 and 3 above may be withdrawn at any time in the best interests of the person concerned.

## *Article 7*

### *Protection of persons who have mental disorder*

Subject to protective conditions prescribed by law, including supervisory, control and appeal procedures, a person who has a mental disorder of a serious nature may be subjected, without his or her consent, to an intervention aimed at treating his or her mental disorder only where, without such treatment, serious harm is likely to result to his or her health.

## *Article 8*

### *Emergency situation*

When because of an emergency situation the appropriate consent cannot be obtained, any medically necessary intervention may be carried out immediately for the benefit of the health of the individual concerned.

## *Article 9*

### *Previously expressed wishes*

The previously expressed wishes relating to a medical intervention by a patient who is not, at the time of the intervention, in a state to express his or her wishes shall be taken into account.

### Chapter III

#### *PRIVATE LIFE AND RIGHT TO INFORMATION*

##### *Article 10*

###### *Private life and right to information*

1. Everyone has the right to respect for private life in relation to information about his or her health.
2. Everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be so informed shall be observed.
3. In exceptional cases, restrictions may be placed by law on the exercise of the rights contained in paragraph 2 in the interests of the patient.

### Chapter IV

#### *HUMAN GENOME*

##### *Article 11*

###### *Non-discrimination*

Any form of discrimination against a person on grounds of his or her genetic heritage is prohibited.

##### *Article 12*

###### *Predictive genetic tests*

Tests which are predictive of genetic diseases or which serve either to identify the subject as a carrier of a gene responsible for a disease or to detect a genetic predisposition or susceptibility to a disease may be performed only for health purposes or for scientific research linked to health purposes, and subject to appropriate genetic counselling.

##### *Article 13*

###### *Interventions on the human genome*

An intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants.

#### *Article 14*

##### *Non-selection of sex*

The use of techniques of medically assisted procreation shall not be allowed for the purpose of choosing a future child's sex, except where serious hereditary sex-related disease is to be avoided.

#### Chapter V

### *SCIENTIFIC RESEARCH*

#### *Article 15*

##### *General rule*

Scientific research in the field of biology and medicine shall be carried out freely, subject to the provisions of this Convention and the other legal provisions ensuring the protection of the human being.

#### *Article 16*

##### *Protection of persons undergoing research*

Research on a person may only be undertaken if all the following conditions are met:

- (i) there is no alternative of comparable effectiveness to research on humans,
- (ii) the risks which may be incurred by that person are not disproportionate to the potential benefits of the research,
- (iii) the research project has been approved by the competent body after independent examination of its scientific merit, including assessment of the importance of the aim of the research, and multidisciplinary review of its ethical acceptability,
- (iv) the persons undergoing research have been informed of their rights and the safeguards prescribed by law for their protection,
- (v) the necessary consent as provided for under Article 5 has been given expressly, specifically and is documented. Such consent may be freely withdrawn at any time.

#### *Article 17*

##### *Protection of persons not able to consent to research*

1. Research on a person without the capacity to consent as stipulated in Article 5 may be undertaken only if all the following conditions are met:

- (i) the conditions laid down in Article 16, sub-paragraphs (i) to (iv), are fulfilled;
- (ii) the results of the research have the potential to produce real and direct benefit to his or her health;